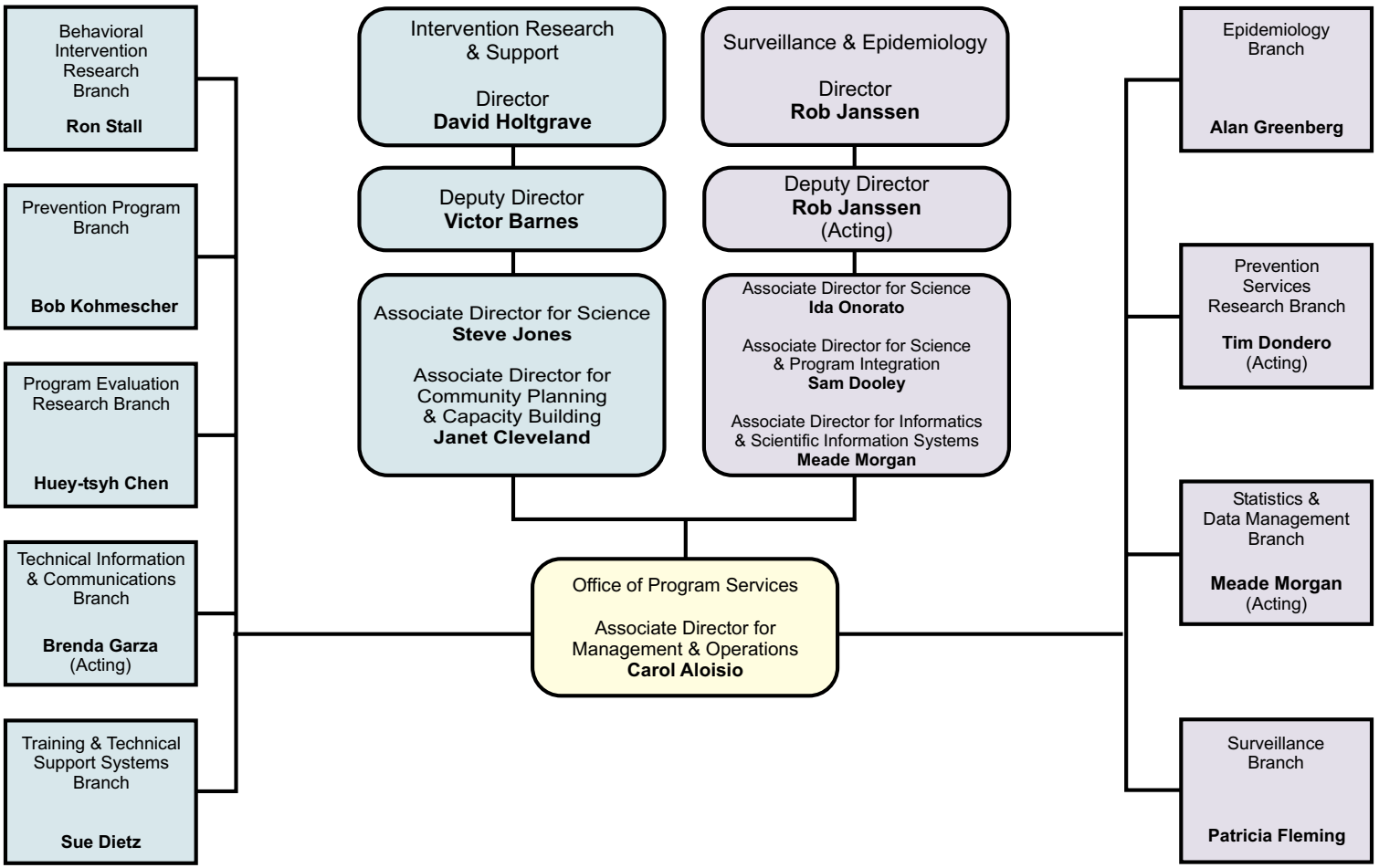
Divisions of HIV/AIDS Prevention



CDC's HIV Prevention Strategic Plan

Background: CDC has completed a two-year process to develop a strategic plan for HIV prevention. The plan crosses all components of CDC that are engaged in HIV activities, including the National Center for HIV, STD, and TB Prevention, which has the bulk of the agency's HIV portfolio; the National Center for Chronic Disease Prevention and Health Promotion, which houses the Division of Adolescent and School Health as well as the Division of Reproductive Health; and the National Center for Infectious Diseases, which conducts a number of important lab-based studies of the virus and possible biomedical interventions, including vaccines.

The plan was developed in conjunction with our external partners and sister public health service agencies.

Accomplishments: The HIV prevention strategic plan encompasses CDC's domestic and international activities. Its overarching domestic goal is to cut new domestic infections in half — from 40,000 to 20,000 annually by the year 2005. To accomplish these activities, it has four national goals and one international goal:

- Decrease by at least 50% the number of persons in the United States at high risk for acquiring or transmitting HIV infection by delivering targeted, sustained and evidence-based HIV prevention interventions.

- Through voluntary counseling and testing, increase from the current estimated 70% to 95% the proportion of HIV-infected people in the United States who know they are infected.

- Increase from the current estimated 50% to 80% the proportion of HIV-infected people in the United States who are linked to appropriate prevention, care and treatment services.

- Strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions and evaluate prevention programs.

- Assist in reducing HIV transmission and improving HIV/AIDS care and support in partnership resource-constrained countries (international goal -- see GAP section).

Challenges: Clearly, accomplishing these domestic goals will require close collaboration with other HHS agencies, including HRSA, SAMHSA, NIH, and HCFA, but also with the state and local partners. Representatives from other HHS components were involved in creating the plan; we have had ongoing conversations with them about developing action steps to make the plan a reality; and we will continue that dialogue to ensure maximum effectiveness and to avoid duplication of effort.

Under the first accomplishment, the top 5 priority populations are:

- Individuals who are already HIV infected;
- Men who have sex with men;
- Adolescents;
- Injecting drug users; and
- At-risk sexually active women and heterosexual men.

SAFE, A Serostatus Approach to Fighting the HIV/AIDS Epidemic

Background: CDC has announced an expanded approach to HIV prevention that involves extensive prevention outreach and services to those living with the disease. Every new HIV infection is the result of a seropositive individual inadvertently transmitting the virus. CDC believes that those who are unaware of their HIV status — and consequently not receiving prevention and care services — are contributing significantly to new HIV infections.

Because of treatment advances, more people with HIV infection are living longer and better lives. Services and interventions for high-risk negative persons may not address the needs of the HIV infected. The goals of SAFE (Serostatus Approach to Fighting the Epidemic) are now included throughout CDC's HIV Prevention Strategic Plan.

SAFE, initially focuses on expanding voluntary counseling and testing programs to reach all individuals living with HIV infection, including the estimated 200,000 - 275,000 Americans who are infected with HIV, but don't yet know it. There are several reasons to intensify efforts to reach infected individuals. First, individuals who know they are infected can benefit from prophylaxis for opportunistic infections, monitoring of their immune status, antiretroviral therapy (when recommended), and, if needed, substance abuse and/or mental health treatment. Second, studies indicate that after learning their HIV status, most infected individuals take steps to protect their partners. Third, new HIV therapies, by lowering viral load, may reduce the degree of infectiousness. While antiretroviral therapy will not eliminate transmission of HIV, it could reduce it. At a population level, if risk behavior (condom use, sexual practices, and number of partners) remain unchanged, this reduction in transmissibility could significantly impact the course of the epidemic. Because antiretroviral therapy can have toxic and adverse physical side effects, decisions about when to initiate use of these drugs should be made by the person living with HIV in consultation with their physician.

Through targeted awareness and testing programs, SAFE will focus on significantly increasing the number of infected people who learn their HIV status through voluntary testing (with a goal of 30,000 per year). High-risk individuals who test negative, particularly those whose partners are living with HIV, will be referred to prevention programs to help them stay uninfected.

The following four additional SAFE action steps target individuals who test positive for HIV:

- Increasing the number of infected individuals who are referred to, and continue to utilize, care and treatment services.

- Facilitating quality care and treatment by linking infected individuals to care, continually updating relevant guidelines and monitoring the quality and utilization of care [Health Resources and Services Administration (HRSA) is the lead federal agency for HIV treatment in the U.S.].

- Helping those living with HIV improve adherence to treatment regimens.

- Supporting individuals living with HIV, and their partners, to adopt and sustain life-long HIV and STD risk reduction behaviors.

SAFE expands upon existing prevention efforts, it does not replace them. Traditional HIV prevention efforts, proven to change behaviors and decrease risk among high-risk HIV-negative individuals, will remain a fundamental part of CDC's HIV prevention portfolio.

SAFE (continued)

Accomplishments: Current studies which will be used to advance SAFE include:

- Project HEART (Helping Enhance Adherence to Antiretroviral Therapy) is a clinic-based behavioral intervention for HAART-naive patients;

- ARTAS (Antiretroviral Treatment and Access Studies) involves case management to improve HAART access among newly diagnosed seropositives;

- Partnership for Health (Brief Safer Sex and Adherence Intervention for HIV Outpatient Clinics) is an intervention at level of care encouraging providers to promote safer sex and adherence among patients;

- SUMIT (Seropositive Urban Men's Intervention Trial) is a behavioral intervention trial to reduce risk of HIV transmission by HIV-positive men who have sex with men (MSM) and to increase disclosure of positive status to sexual partners.

- PHIPP (Prevention for HIV-Infected Persons Project) consists of five health department/CBO projects of various interventions to reduce HIV transmission by HIV-positive persons and includes coordinated evaluation. The PHIPP project is now in its third year and information is becoming available to share with others;

- INSPIRE (Interventions for SeroPositive IDUs: Research & Evaluation) is a behavioral intervention for intravenous drug users (IDUs) to lower sexual and drug use risk, increase access to care, and increase adherence to HAART regimens. The goals of INSPIRE include:

    - Decrease unprotected sexual behavior with uninfected partners.
    - Decrease drug injection and needle sharing with uninfected partners.
    - Facilitate consistent access to and utilization of appropriate medical care.
    - Improve adherence to medical treatments including HAART.

- In addition, CDC funded 20 projects to develop community coalitions to facilitate referrals to care and prevention services.

- In the health department HIV prevention applications for 1999, only one-third identified persons living with HIV infection as a priority population. In the continuation applications for FY 2001, nearly 58% identified this population as a priority.

- In FY 2000, CDC awarded funds to 34 CBOs to identify people of color at increased risk of infection, to encourage them to seek testing, and provide testing, counseling, and referral in settings most accessible to the target population.

Challenges:

- Increase the proportion of HIV-infected people in the U.S. who know they are infected from the current 70% to 95%;
- Increase the proportion of HIV-infected people who are linked to appropriate care, prevention services, and treatment services from the current estimated 50% to 80% by;
- Gain endorsement of SAFE by federal partners and implementation by their constituents; and
- Increase the number of established prevention programs for HIV positives in the state systems and community. Currently only about 40% of community programs target HIV-positive persons.

New HIV Counseling, Testing, and Referral Guidelines: Implications and Implementation

Background: As mentioned, SAFE initially focuses on expanding voluntary counseling and testing to reach all individuals living with HIV infection, including those who don't yet know they are infected. CDC's new HIV Counseling, Testing, and Referral Guidelines serve as a tool to understand the science and "best practices" regarding HIV counseling, testing, and referral – or CTR. They also guide policy recommendations at the federal, state, and local levels and facilitate development and implementation of high quality prevention services. The previous standards and guidelines, published in 1994, focused on services provided by publicly funded providers and presented basic tenets of HIV counseling and testing: testing should be informed, voluntary, and consented; both confidential and anonymous testing should be available; and clients should have access to information on HIV testing and transmission. Counseling was focused on "client-centered" counseling models, an interactive risk-reduction model, in which the counselor helps the client identify and acknowledge personal HIV risk behaviors, and commit to a single, achievable behavior change that could reduce the client's HIV risk.

Accomplishments: In 2001, the new HIV Counseling and Testing Guidelines will be published this Spring in the *MMWR Recommendations and Reports*.

- The new guidelines reflect current evidence-based practices and, where evidence was lacking, they reflect expert opinion. The goals of the new guidelines are to ensure that persons with HIV infection and persons with increased risk receive high quality HIV prevention counseling to reduce their risk of transmitting or acquiring HIV; have early knowledge of their HIV status; and have access to appropriate services. The guidelines also promote early knowledge of HIV status through HIV testing and ensure that all persons recommended or requesting HIV test services receive information about HIV transmission and prevention, as well as HIV test specifics.

- The new guidelines still recommend that HIV testing should be informed, voluntary, and consented and available as confidential and anonymous testing services. In addition, there is continued emphasis on access to testing and provision of test results to clients. Counseling should be "client-centered." However, the new guidelines expand the audience from publicly funded providers to include all providers of HIV testing services.

- They encourage testing to learn HIV serostatus. They expand recommendations on referral methods and services and quality assurance. In addition, because CTR services are offered in a variety of settings, the new guidelines recognize the need for flexibility. A publicly funded, dedicated HIV CTR site in a high-prevalence area, for example, has different needs than a private HMO in a low-prevalence area.

- Practitioners are allowed to tailor the guidelines to better serve their clients. They can use these recommendations to optimize counseling and testing procedures (such as the use of phone counseling or rapid tests to ensure the return of test results); to maximize coverage and participation of HIV CTR services using "risk screening" strategies to target prevention services to persons at increased HIV risk; and to prioritize care and referral services for populations at increased risk dependant on prevalence, risk population, setting, and symptomatology.

Challenges: The expansion of the guidelines to include providers may make implementation more difficult. For example:

- The new guidelines are not standards and are not mandatory. However, the guidelines are science based, and should be considered for use by all providers, depending on where and how HIV CTR services are provided;

- Practitioners and providers will need training and technical assistance to aid in the use of these guidelines so that the new recommendations are as useful as the earlier standards;

- Since the new guidelines offer increased flexibility, evaluation and QA protocols will need to be developed on an individual basis. Programs, and even different sites within a program, may need different evaluation and quality assurance systems.

Prevention Services to Communities of Color

Background: CDC has awarded funds through supplements to cooperative agreements to address prevention needs in communities of color disproportionately affected by the HIV epidemic. Factors considered in these awards decisions are AIDS prevalence, geographical location, target population, and risk behavior. In addition, through the Minority AIDS Initiative (Congressional Black Caucus) and the Secretary's Emergency Fund, CDC has awarded funds to community-based organizations targeting services to communities of color. CDC provided funds for:

- Organizations with a history of providing services to the African-American community to target high-risk populations of women, youth, and men;
- Creation of new community development grants to 20 African-American communities highly impacted by HIV/AIDS;
- Technical assistance provided by national, regional, and local minority organizations to directly funded minority community-based organizations; and
- A faith-based initiative to develop HIV and substance abuse prevention training grants and curriculum at the divinity schools of the historically black colleges and universities.

Accomplishments: Part of the spirit of the minority initiative was to fund as many new minority organizations as possible. Of the 210 awards made to minority CBOs, only 20% were made to organizations previously funded by CDC under program announcement 704. Only 33 organizations received more than one award.

- The review process has been improved. It is now more efficient, comprehensive, and ensured the composition of the reviewers mirrored the national HIV epidemic. New rules were established that would allow CDC to make adjustments to ensure that awards also mirrored the HIV epidemic by race/ethnicity, risk behavior, and geographic impact.
- CDC has also undertaken a program to provide much needed capacity-building assistance. Providing financial assistance to minority CBOs is not enough. Funding needs to be accompanied by a comprehensive process to strengthen their capacity. This process was reorganized from previous efforts to cover the following areas: 1) strengthening organizational infrastructure; 2) enhancing intervention design, development, implementation and evaluation; 3) strengthening community capacity; and 4) strengthening HIV prevention community planning.
- Under the capacity-building program, CDC made 39 awards to 27 minority CBOs. This process ensured a distribution of services by race/ethnicity, risk behavior, and geographic impact. CDC has also hired additional FTEs, provided ongoing training to project officers, lowered the project officer caseload, and is developing evaluation and reporting guidance.
- HIV prevention community planning was strengthened to better incorporate the needs of communities of color.

Challenges: Although the minority initiative was able to reduce the gap in the number of available services to minority communities, a number of critical challenges remain. These include:

- Assisting organizations in increasing their sustainability and capacity, developing evaluation tools, and analyzing data;
- Continuing to identify and transfer effective interventions;
- Assisting the minority CBOs in strengthening their collaboration with health departments and community planning groups; and
- Addressing the needs and improving services to underrepresented populations (such as MSM).

Prevention Services for Men Who Have Sex With Men

Background: Of the total number of AIDS cases, 53% are among men who have sex with men (MSM). From July 1999 to June 2000, 37% of the adult and adolescent AIDS cases reported were among MSM.

Accomplishments:

- For FY 2001, 64% of the health department HIV prevention project areas listed MSM as their primary target population and 83% listed MSM within their top three priorities.
- A qualitative summary of STD/HIV surveillance and behavioral trends is currently being developed to assistant constituents by providing them with the most recent trends in STD and HIV morbidity and risk behaviors among MSM.
- Guidelines for improving HIV/STD programs for MSM by addressing increases in unsafe behaviors among MSM are currently under development for use by CDC grantees and partners providing services to MSM populations.
- A series of three regional trainings will take place later this year to assist constituents in ways through which HIV/STD services for MSM can be improved.
- A satellite video-conference entitled, HIV Prevention Update: Men Who Have Sex with Men, which addressed trends in risk-taking behavior and HIV/AIDs among MSM as well as highlighting effective prevention programs for this population, was broadcast nationwide.
- Over the past two years, CDC has provided funds for HIV prevention for MSM through several program announcements, including: 99091 “Gay Men of Color” (30 CBOs), and 00023 “HIV Prevention Projects for CBOs” (34 of the 84 funded CBOs proposed to target MSM). Altogether, more than $7.5 million was awarded to 37 national, regional and community-based organizations to supplement the pool of existing prevention programs targeting MSM of color.
- Several CDC research studies are currently underway to evaluate the effects of innovative interventions for ethnically diverse groups of young MSM and HIV seropositive MSM. Examples include Community Intervention Trial for Youth (CITY) Project, which is a 13-community study that will evaluate a multi-component HIV prevention intervention for young African-American, Asian/Pacific Islanders, Latino and white MSM who are between 15 and 25 years of age.

Challenges:

- There are indications that gay men are becoming increasingly complacent due to: 1) the apparent success of the HAART regimen; 2) prevention fatigue; 3) changes in mixing patterns; 4) demographic changes, e.g., changes in age; and 5) sexually active persons living with HIV infection;
- More prevention research is needed. In CDC’s Compendium of Prevention Interventions only 5 of the 24 highlighted studies focused on gay men;
- Interventions may not be keeping pace with changing circumstances in MSM communities;
- CBOs serving gay men of color tend to be younger and more in need of infrastructure support.

Building Capacity, Technology, Transfer Efforts, and Sustainability for HIV Prevention

Background: HIV prevention capacity building is a process by which individuals, organizations, and communities develop abilities to enhance and sustain HIV prevention efforts. The goal of capacity building is to foster self-sufficiency and the self-sustaining ability to improve HIV prevention programs, processes, and outcomes. Capacity building involves a variety of delivery mechanisms: 1) technology transfer; 2) technical/capacity-building assistance; 3) training; 4) skills building; and 5) information dissemination.

Accomplishments: CDC's capacity-building efforts are focused in four areas:

- Strengthening organizational infrastructure;
- Enhancing HIV prevention interventions;
- Mobilizing communities for HIV prevention; and
- Strengthening HIV prevention community planning.

CDC's technology transfer efforts are evolving to help build the capacity of grantee organizations and affected communities in enhancing and sustaining their HIV prevention efforts. Examples include:

- Replicating effective programs;
- Compendium of HIV prevention interventions; and
- Characteristics of reputationally strong programs.

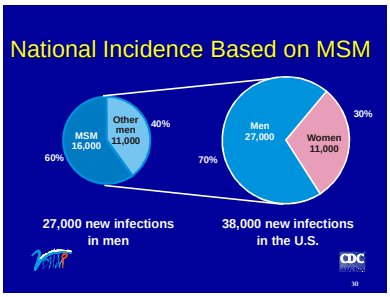
In October 2000, CDC met with staff of the National Institute of Minority Health (NIMH) to examine ways to increase the translation of research-based knowledge into practical behavioral interventions and to increase the effectiveness of community-based organizations in launching science-based prevention programs. This meeting resulted in the following recommendations:

- Research for MSM is outdated for current prevention efforts;
- There is a need to develop a systematic approach to technology transfer and to implement a model for intervention adoption;
- Researchers should be involved with communities beyond the publication of their findings;
- Technical assistance processes should be monitored in a way that can inform the next generation of research; and
- CDC and NIMH should fund proposals requiring equal control of research implementation by researchers and CBOs.

Challenges: Major challenges include:

- Fostering further linkages with NIH in the delivery of science-based HIV prevention interventions by supporting demonstration projects of joint technical assistance in HIV prevention intervention technology;
- Developing technical assistance and training systems to impart tools of cost-effectiveness analysis to local, state, and national-level funding decision makers;
- Expanding technical assistance to state and local health departments and CBOs in the use of HIV incidence, STD, and risk behavior data to make funding allocation decisions; and
- Conducting research designed to determine the best methods for delivering technical assistance to HIV prevention service delivery organizations with a special emphasis on organizations providing services to communities of color.

Estimating HIV Incidence in the United States



Background: The overarching national goal of the new CDC HIV Prevention Strategic Plan is to "reduce the number of new HIV infections per year in the United States from an estimated 40,000 to 20,000 per year by the year 2005." A major new direction of CDC's activities in the next year will be developing ways to measure the number of new infections. CDC will use a national estimate of HIV incidence to measure progress toward the overarching goal of the HIV Prevention Strategic Plan. Knowing the number of infected persons and particularly following the trends will assist policymakers in setting national priorities for AIDS prevention programs and will help justify and allocate resources.

Accomplishments: CDC is currently conducting incidence studies, research, and consultations.

- A major advance in our ability to measure new infections came with the development of the detuned assay. Using the detuned assay, new HIV infection can be determined on a single blood specimen by taking advantage of the fact that in early infection, antibody levels are lower than later in infection. Thus, CDC may be able to estimate national incidence by detuning specimens collected from persons who have been newly diagnosed with HIV in states that have HIV reporting, or in pregnant women, or in persons from whom blood is obtained in NHANES (a nationally representative population-based survey).

- CDC's Divisions of HIV/AIDS Prevention - Intervention Research and Support, and Surveillance and Epidemiology, have funded five health departments to conduct studies of innovative approaches to determining incidence. These health departments are using the detuned assay to test blood from voluntary counseling and testing sites and blinded surveys of MSM, IDU, high-risk heterosexuals and prisoners.

- There is also a need for new tests that may be simpler to perform and more readily available than the Abbott detuned assay. CDC's Division of AIDS, STD and TB Laboratory Research in NCID is working on a new assay that relies on increases in the proportion of total IgG that is HIV specific with time since infection. CDC's Divisions of HIV/AIDS Prevention - Intervention Research and Support, and Surveillance and Epidemiology, are also funding laboratories in Massachusetts and Australia to develop new assays and to adapt the detuned assay for use with oral fluid. This would be very useful for community-based assessments of incidence.

- A technical consultation on estimating incidence was held in February 2001. This consultation was to explore possible methods, and look at the feasibility, cost, and precision of the different methods and their applicability for national and local estimates.

Challenges: Determining the best method to use for estimating incidence is crucial. The precision of the estimate and the ability to follow trends is crucial to using incidence estimates to evaluate prevention programs and should be a key consideration in method selection. Possible methods include:

- The "top-down" approach would develop studies that will obtain a national estimate and then try to derive local estimates. However, a national approach may not sample enough persons or may have too few HIV infections in a given area to produce a local estimate for that area. Risk information may be unavailable if, for example, only pregnant women are tested;

- If we take the "bottom-up" approach and fund health departments to conduct studies aimed at producing local area estimates, such as detuning STD clinic or counseling and testing specimens, we would need to perform complex modeling to make a national estimate. A criticism of this approach is that it only accesses persons who present for HIV or STD testing or drug treatment;

- There are a number of other issues to be considered depending on the approach, including ensuring the ethical conduct of blinded surveys, the feasibility and cost of any new studies, and different needs for community planning and preventive services in different areas which may require the use of non-standardized local protocols;

- All the approaches have biases and problems with not representing all groups for which we would like information.

Evaluation Guidance to State/Local Health Departments and CBOs

Background: The purpose and rationale of the health department evaluation guidance is to report, improve and identify improvement mechanisms. The health department evaluation guidance is designed:

- To provide information needed to report to federal, state and local stakeholders;
- To improve HIV prevention policies;
- To better target resources for those disproportionately affected and infected with HIV; and
- To help improve HIV prevention programs by identifying the most appropriate mechanisms needed, such as funding, evaluation or capacity-building.

During various stages of guideline development, CDC has held a number of face-to-face meetings with evaluation experts and primary stakeholders, such as NASTAD, health departments, and CBOs. In addition, CDC has also conducted pilot testing on the data collection instruments and incorporated revisions. The evaluation guidance package was submitted to OMB for review.

The guiding principle used for the development of the CBO evaluation guidance is based on the need for consistency with the health department evaluation guidance. Because some CBOs are funded directly by health departments, some are funded directly by CDC, and some are funded by both, a similar evaluation guidance was needed so that CBOs were not reporting information under two different systems. The evaluation guidance will provide:

- Impact evaluation: an assessment of the cumulative effect of HIV prevention efforts on HIV transmission at the local and national levels; and
- Impact evaluability assessment: an assessment of the feasibility of conducting impact evaluation, given the current HIV prevention structure and data systems.

Accomplishments:

- In February and March 2000, over 130 persons representing 65 jurisdictions participated in one of five health department evaluation guidance training sessions. CDC established and strengthened collaborative mechanisms to provide and implement technical assistance. Supplemental funding ($100,000) for evaluation was provided to each health department jurisdiction receiving $1 million or more in CDC HIV prevention funding. CDC posted the Health Department Evaluation Guidance on the CDC Web site so it was easily available to constituents;

- Data collection is underway in health departments for FY 2001. Health departments have been quite receptive to implementing an evaluation component to their programs. Many have set up additional training sessions in their jurisdiction with their grantees to begin implementing the guidance;

- Within DHAP, an in-house MS-access-based system called Evaluation Reporting and Analysis System (ERAS) will facilitate processing, validating and reporting of evaluation activity data; and

- The CBO evaluation guidance is in the final stages of development. We anticipate sending it to OMB within the month.

Challenges: In light of all these accomplishments, we face many future challenges:

- Data submission issues highlight the importance of expanding the quality assurance system, so that quality assurance activities are interdependent and integrated into ongoing collection, analysis, interpretation, and dissemination of program evaluation data;
- In preparing to launch the web-based data collection mechanism, issues such as confidentiality and the proper use of data in a careful manner will need to be considered; and
- There will be a need for additional supplemental evaluation training and resources to sustain and expand current health department program evaluation infrastructures.

Synthesizing Behavioral Data to Inform Prevention Planning

Background: In state- and local-level prevention planning, there is a need for behavioral data that monitors behaviors associated with risk of infection, HIV testing, care seeking, and adherence. In 1997, CDC received one-time funding to develop a sexual behavior module to the Behavioral Risk Factor Surveillance System (BRFSS). The results of this information on risk behavior can help identify specific behaviors and population subgroups engaging in those behaviors and locations where interventions are needed. CDC can use ongoing data on risk behavior to evaluate the impact of prevention programs.

Accomplishments: Behavioral surveillance has included sentinel events in disease surveillance, sentinel behaviors in behavioral surveillance and identification of populations in which to apply an integrated model. CDC has estimated risk behaviors among sexually active men and women using the BRFSS. Through the HIV Testing Survey II (HITS-II) and Supplement to HIV/AIDS Surveillance (SHAS) surveys, we have obtained behavioral risk factors and perceptions among HIV-infected heterosexuals, MSM, IVDUs and non-infected heterosexuals. Information is also available on the percent of persons tested within two months of AIDS diagnosis, trends in HIV diagnoses by stage of disease, percentage of respondents who have ever tested for HIV, trends in prescribed use of antiretroviral therapy, and self-reported adherence to highly active antiretroviral therapy (HAART) among HIV-infected persons. This behavioral data can guide secondary prevention efforts by identifying barriers to adherence. This, in turn, helps prevent the emergence of resistant strains and improves health and survival.

Challenges: To better meet the needs of state/local areas, challenges include:

- The capacity at state and local levels to conduct behavioral studies;
- The capacity in state and local planning groups to effectively use behavioral data in epidemiologic profiles;
- Current limited general population surveys to provide high quality awareness and attitude data; and
- Infrastructure needs to be built to facilitate public health-academic collaborations in partnership with communities in order to collect relevant behavioral data for special populations.

HIV Vaccine Research

Background: There have been more than 70 Phase I & II human clinical trials of HIV vaccine in the world, only 11 of which have taken place in developing countries where most of the disease burden can be found. Of those, only one product, the VaxGen AIDS product, has advanced to Phase III trials, and CDC is playing a key role in these trials in the U.S. and Thailand.

Accomplishments: CDC's current activities in HIV vaccine research focus on vaccine trials:

- The VAX004 trial is the VaxGen AIDSVAX B/B efficacy trial taking place primarily in North America. The collaborators are VaxGen, the manufacturer and trial sponsor, 61 local sites around the U.S., and CDC and NIH. The population being tested is 5,109 MSM and 309 high-risk women. The product is a recombinant vaccine (rgp120: B[MN] / B[GNE8]). The schedule calls for doses at 0, 1, and 6 months, followed by booster doses at 12, 18, 24, and 30 months. Its design is two-thirds vaccine and one-third placebo. The duration is three years, with a start date of June 1998, and a full enrollment in October 1999. The first formal look at efficacy will take place in November 2001. The primary outcome of this trial is a simple "HIV infection: yes or no."

- The VAX003 trial is the VaxGen AIDSVAX B/E efficacy trial taking place in Thailand. The collaborators are VaxGen, the manufacturer and trial sponsor, the Bangkok Metropolitan Administration, Mahidol University, and CDC through its collaboration with the Thai Ministry of Public Health. The population being tested is 2,540 injection drug users in Bangkok. The product is a recombinant vaccine (rgp120: B[MN] / E[A244]). The schedule calls for doses at 0, 1, and 6 months, followed by booster doses at 12, 18, 24, and 30 months. Its design is one-half vaccine and one-half placebo. The duration is three years, with a start date of March 1999, and a full enrollment in August 2000. The first formal look at efficacy will take place in early 2002.

- The vaccine trials in the U.S. and Thailand are proceeding well. Completion is estimated for the U.S. in October 2002, and August 2003 for Thailand. CDC's role in the trials will be to interpret and communicate results; determine if the vaccine is effective, for what subtypes, for how long, and for what exposures; consult on implementation strategies and access; and consult on the design of the next generation of vaccines and trials.

- CDC is also supporting HIV vaccine development for West Africa. NCHSTP is working with Emory and NCID in the development of an HIV-1 subtype A/G DNA + MVA vaccine. CDC is assisting in site preparation in Côte d'Ivoire as part of Project RETRO-CI.

Challenges: Future challenges in HIV vaccine development include the development of a strategic plan with the following elements:

- In the development of an HIV vaccine, collaborations must be established (NIH, DOD, IAVI, UNAIDS) to develop appropriate vaccines for use in international sites in West, East, and Southern Africa, and Asia;
- In evaluating an HIV vaccine, CDC must explore other populations in the U.S. for efficacy trials (heterosexual men & women, minorities) and develop new sites for efficacy trials such as Kenya and other sites in Africa;
- Communications with communities about vaccines should be expanded;
- Strategies should be developed and implemented, including: 1) preparing for results from efficacy trials; 2) finding a use for a partially protective HIV vaccine (what risk groups? should it be used in the U.S.? should it be used internationally?); and 3) assuring universal access (UNAIDS); and
- HIV testing will be more complex in the era of HIV vaccine trials, including distinguishing HIV vaccine-induced antibodies from true infection and implications for CTR guidelines.

Key Research Findings

Incidence of Cervical Squamous Intraepithelial Lesions in HIV-Infected Women

Authors: Ellerbrock TV, Chiasson MA, Bush TJ, Sun XW, Sawo D, Brudney K, Wright TC Jr.
Source: *Journal of the American Medical Association*, 2000 February 23;283(8):1031-7.

Women infected with human immunodeficiency virus (HIV) are at increased risk for cervical squamous intraepithelial lesions (SILs), the precursors to invasive cervical cancer. However, little is known about the causes of this association. This research compared the incidence of SILs in HIV-infected versus uninfected women and determined the role of risk factors in the pathogenesis of such lesions. A prospective cohort study was conducted from October 1,1991, to June 30, 1996, in urban clinics for sexually transmitted diseases, HIV infection, and methadone maintenance. A total of 328 HIV-infected and 325 uninfected women with no evidence of SILs by Papanicolaou test or colposcopy at study entry were studied. The outcome measure was to determine incident SILs confirmed by biopsy, compared with HIV status and risk factors. During 30 months of follow-up, 67 (20%) HIV-infected and 16 (5%) uninfected women developed a SIL (incidence of 8.3 and 1.8 cases per 100 person-years in sociodemographically similar infected and uninfected women. Of incident SILs, 91% were low grade in HIV-infected women versus 75% in uninfected women. No invasive cervical cancers were identified. The results indicated significant risk factors for incident SILs were HIV infection, transient human papillomavirus (HPV) DNA detection, persistent HPV DNA types other than 16 or 18, persistent HPV DNA types 16 and 18, and younger age (<37.5 years). In this study, 1 in 5 HIV-infected women with no evidence of cervical disease developed biopsy-confirmed SILs within 3 years, highlighting the importance of cervical cancer screening programs in this population.

Drug Safety During Pregnancy and in Infants: Lack of Mortality Related to Mitochondrial Dysfunction Among Perinatally HIV-Exposed Children in Pediatric HIV Surveillance

Authors: Lindegren ML, Rhodes P, Gordon L, Fleming P, State and Local Health Department HIV/AIDS Surveillance Programs, and the Perinatal Safety Review Working Group
Source: *Annals of the New York Academy of Sciences*, November 2000, Volume 918, Prevention and Treatment of HIV Infection in Infants and Children.

The objectives of this study were to assess whether any deaths reported among perinatally exposed, uninfected, or indeterminate children were consistent with mitochondrial dysfunction, and to characterize perinatal exposure to antiretrovirals among children born in the last five years and reported to perinatal HIV surveillance. Population-based HIV/AIDS surveillance data was used for perinatally exposed children born in 1993 through 1998 from 32 states with HIV reporting and from a special HIV surveillance project in Los Angeles County and in 22 hospitals in New York City. The classifications of exposure and deaths were consistent with the investigation of deaths across all U.S. cohorts. Deaths were ascertained from recent matches with death registries in each state. Causes of death were ascertained from death certificates, autopsy records when available, and medical records. None of the 98 deaths (1.1%) among 9067 perinatally exposed uninfected or indeterminate children born from 1993 through 1998 and reported through pediatric HIV surveillance died of conditions that were consistent with mitochondrial dysfunction. This included 679 children exposed to zidovudine (ZDV) and 3TC, 277 exposed to other antiretroviral combinations, 4512 exposed to ZDV alone, 927 with no antiretroviral exposure, and 2672 with unknown exposure—1128 of whom were born before March 1994 and were unlikely to have been exposed to ZDV. No deaths attributable to mitochondrial dysfunctions were found through this evaluation of population-based HIV surveillance data. Long-term follow-up of antiretroviral-exposed children has been recommended by the Public Health Service. This evaluation highlights the contribution of population-based surveillance to the evaluation of potential toxicities associated with maternal antiretroviral use.

Nucleoside Exposure in the Children of HIV-Infected Women Receiving Antiretroviral Drugs: Absence of Clear Evidence of Mitochondrial Disease in Children Who Died Before 5 Years of Age in Five United States Cohorts

Authors: The Perinatal Safety Review Working Group
Source: *Journal of Acquired Immune Deficiency Syndromes*, 25:261-268.

Nucleoside reverse transcriptase inhibitors (NRTIs) have been associated with mitochondrial toxicity in individuals receiving treatment. A report of two deaths in Europe attributed to mitochondrial dysfunction in HIV-uninfected infants with perinatal NRTI exposure prompted a review of five U.S. cohorts. Deaths in HIV-exposed children <60 months of age and HIV-uninfected or indeterminate were reviewed. Review included birth history; perinatal antiretroviral drug exposure; hospital, laboratory, and clinic records; death reports; autopsy results; and local physician queries. Deaths were classified as unrelated, unlikely related, possibly related, or highly suggestive or proven relationship to NRTIs. Sudden infant death syndrome (SIDS) was categorized separately. Among over 20,000 children of HIV-infected women, over half of whom had been exposed to NRTIs, 223 died. In HIV-uninfected children, 26 deaths were attributed as unrelated to mitochondrial dysfunction and 4 were attributed to SIDS. In HIV-indeterminate children, 141 were unrelated to NRTIs, 10 were unlikely related, 3 were possibly related and 0 were highly suggestive or proven relationship with NRTIs; 33 were due to SIDS and 6 could not be classified. There was no indication that antiretroviral exposure was associated with unlikely related or possibly related deaths, or deaths from SIDS. A search for mitochondrial dysfunction among living children in these cohorts is ongoing.

Prevalence of Mutations Associated with Reduced Antiretroviral Drug Susceptibility Among Human Immunodeficiency Virus Type 1 Seroconverters in the United States, 1993-1998

Authors: Weinstock H, Respess R, Heneine W, Petropoulos CJ, Hellmann NS, Luo CC, Pau CP, Woods T, Gwinn M, Kaplan J
Source: *Journal of Infectious Diseases*, 2000 July; 182(1):330-3.

To assess the prevalence of mutations associated with decreased antiretroviral drug susceptibility, specimens were tested from persons infected with human immunodeficiency virus (HIV) during 1993-1998. Subjects were drug naive and were attending sexually transmitted disease clinics in six U.S. cities. All were enrolled consecutively and had tested negative for HIV during the 2 years before enrollment. Plasma specimens from patients having >/=1 reverse transcriptase (RT) or primary protease mutation were tested phenotypically with a recombinant virus assay. Of 99 patients, 6 (6%) had mutations associated with zidovudine resistance, 2 (2%) had mutations associated with nonnucleoside RT inhibitor resistance, and 1 (1%) had a primary protease mutation. Overall, the prevalence of resistance-associated primary mutations was 5%, although high levels of decreased drug susceptibility (IC(50)s >/=10 times that of a reference virus) were observed in just 1%. These findings confirm the transmission of these mutations to drug-naive persons.

HIV Prevalence and Associated Risks in Young Men Who Have Sex With Men

Authors: Valleroy LA, MacKellar DA, Karon JM, Rosen DH, McFarland W, Shehan DA, Stoyanoff SR, LaLota M, Celentano DD, Koblin BA, Thiede H, Katz MH, Torian LV, Janssen RS
Source: *Journal of the American Medical Association*, 2000 July 12; 284(2)198-204.

Studies conducted in the late 1980s on human immunodeficiency virus (HIV) infection among older men who have sex with men (MSM) suggested the epidemic had peaked; however, more recent studies in younger MSM have suggested continued high HIV incidence. The objective of this study was to investigate the

current state of the HIV epidemic among adolescent and young adult MSM in the United States by assessing the prevalence of HIV infection and associated risks in this population in metropolitan areas. For this research, information was obtained from the Young Men's Survey, which is a cross-sectional, multisite, venue-based survey conducted from 1994 through 1998, including 194 public venues frequented by young MSM in Baltimore, Dallas, Los Angeles, Miami, New York City, the San Francisco Bay Area and Seattle. A total of 3492 15- to 22-year-old MSM who consented to an interview and HIV testing participated. The purpose was to determine the prevalence of HIV infection and associated characteristics and risk behaviors. The results of the study indicated prevalence of HIV infection was high (overall, 7.2%; range for the 7 areas, 2.2%-12. 1%) and increased with age, from 0% among 15-year-olds to 9.7% among 22-year-olds. Multivariate-adjusted HIV infection prevalence was higher among blacks, young men of mixed or other race, and Hispanics compared with whites (referent) and Asian Americans and Pacific Islanders. Factors most strongly associated with HIV infection were being black, mixed, or other race; having ever had anal sex with a man; or having had sex with 20 or more men. Only 46 (18%) of the 249 HIV-positive men knew they were infected before this testing; 37 (15%) were receiving medical care for HIV, and 19 (8%) were receiving medical drug therapy for HIV. Prevalence of unprotected anal sex during the past 6 months was high (overall, 41%; range, 33%-49%). Among these young MSM, HIV prevalence was high, underscoring the need to evaluate and intensify prevention efforts for young MSM, particularly blacks, men of mixed race or ethnicity, Hispanics, and adolescents.

HIV Testing Among the General U.S. Population and Persons at Increased Risk: Information from National Surveys, 1987-1996

Authors: Anderson JE, Carey JW, Taveras S
Source: *American Journal of Public Health*, 2000 July; 90(7):1089-95.

Data from national surveys was used to measure the rate of HIV testing in the general U.S. population and among persons at increased behavioral risk for HIV. Three nationally representative surveys were used: the National Health Interview Survey for 1987 through 1995, the 1995 National Survey of Family Growth, and the 1996 National Household Survey on Drug Abuse. These surveys asked about HIV testing experience and behavioral risks for HIV. Rates of testing were computed for all persons, including those at increased risk for HIV. The results indicated that from 1987 to 1995, the percentage of adults ever tested increased from 16% to 40%. The three surveys were consistent with one another, and all showed much higher rates of testing for persons at increased risk for HIV.

Increasing Condom Use Among Adolescents Through Coalition-Based Social Marketing

Authors: Kennedy MG, Mizuno Y, Seals BF, Myllyluoma J, Weeks-Norton K
Source: *AIDS* 2000, 14:1809-1818

This study evaluated a multimodal social marketing intervention to reduce the sexual transmission of HIV infection among adolescents in Sacramento, California. Five rounds of a cross-sectional random sample telephone survey were conducted from December 1996 to October 1998. The total number of respondents was 1,402. A statistically significant, increasing trend in exposure to the intervention was detected. The number of channels through which an adolescent had been exposed to the intervention was associated with condom use at last sex with main partner and with psychosocial determinants of this behavior. After statistical adjustments for sex, age, and race/ethnicity to make the survey rounds comparable, the proportion of adolescents who had used a condom at last sexual exposure increased 4.3 percentage points over the 1 year intervention period. These results indicate social marketing can be combined with behavioral science to reduce the risk of HIV infection and other sexually transmitted diseases (STDs) among adolescents in a large geographical area.

Replicating Effective Programs: HIV/AIDS Prevention Technology Transfer

Authors: Neumann MS and Sogolow ED
Source: *AIDS Education and Prevention* 12, (Suppl. A): 35-48.

This research focused on the methods used by CDC scientists and original intervention researchers in CDC's Replicating Effective Programs (REP) project to (a) translate some HIV prevention behavioral intervention research into materials with enough detail and clarify that state and community partners can select and implement effective interventions and (b) transfer and support these technologies so that they can be implemented successfully. The experience of the REP project indicates that technology transfer is complex. Interventions need to be adapted to local circumstances. Prevention partners need written materials, training, and technical assistance. Researchers need to collaborate with prevention program providers to develop interventions that are feasible for prevention partners to conduct.

Evaluating National HIV Prevention Indicators: A Case Study in San Francisco

Authors: Page-Shafer K, Kim A, Norton P, Rugg D, Heitgerd J, Katz MH, McFarland W, and the HIV Prevention Indicators Field Collaborative
Source: *AIDS*. 14(13):2015-2026, September 8, 2000.

This research was to field-test the availability, interpretability, and programmatic usefulness of 37 proposed national HIV prevention indicators (HPI) intended to evaluate community-level impact of HIV prevention efforts in San Francisco. HPI were defined for four populations (high risk heterosexuals, injecting drug users, men who have sex with men, and childbearing women) and for four domains (biological, behavioral, service, and sociopolitical). HPI were obtained from existing data sources only. Trends in HPI were examined from 1990 to 1997. Existing data provided 29 (78%) of the 37 proposed HPI; eight HPI were not available because California does not have HIV case reporting. Interpretation was limited for several HPI due to small sample size, inconsistencies in data collection, or lack of contextual information. Data providing behavioral HPI were scarce. HPI were consistent with historical patterns of HIV transmission in San Francisco but also highlighted new and worrisome trends. Notably, HPI identified recent increases in risk for HIV transmission among men who have sex with men. Despite limitations, the proposed national HPI provided evidence of the aggregate effectiveness of prevention efforts in San Francisco.

Syringe Laws and Pharmacy Regulations are Structural Constraints on HIV Prevention in the U.S.

Authors: Taussig JA, Weinstein B, Burris S, Jones TS
Source: *AIDS* 2000, 14(suppl 1): S47-S51.

This research reviewed the legal and regulatory barriers that restrict pharmacy sales of syringes to injection drug users (IDUs). IDUs' access to sterile syringes from community pharmacies in the U.S. is limited by state laws and regulations governing syringe sales. Restricted availability of sterile syringes from pharmacies is a structural barrier that greatly impedes HIV prevention for IDUs, who often share and reuse syringes because they cannot obtain and possess sterile syringes. These high-risk behaviors contribute to the transmission of HIV and other blood-borne pathogens among IDUs, their sexual partners, and their children. In Connecticut, because of high HIV prevalence among IDUs, restrictive syringe laws were changed. After the legal changes in Connecticut, both pharmacy sales of syringes in areas of high drug use and purchases of syringes in pharmacies (reported by IDUs) increased, while syringe sharing (reported by IDUs) decreased. Maine and Minnesota have made similar changes in laws. Based on this research, increasing access to sterile syringes through pharmacies requires the repeal or modification of legal barriers. Pharmacy sale of syringes to IDUs is an inexpensive HIV prevention intervention with the potential to substantially reduce HIV transmission.

Division of HIV/AIDS Prevention - Surveillance and Epidemiology 2000 Publications*

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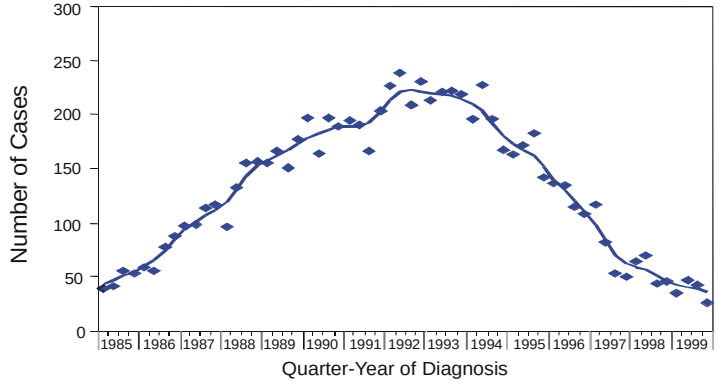
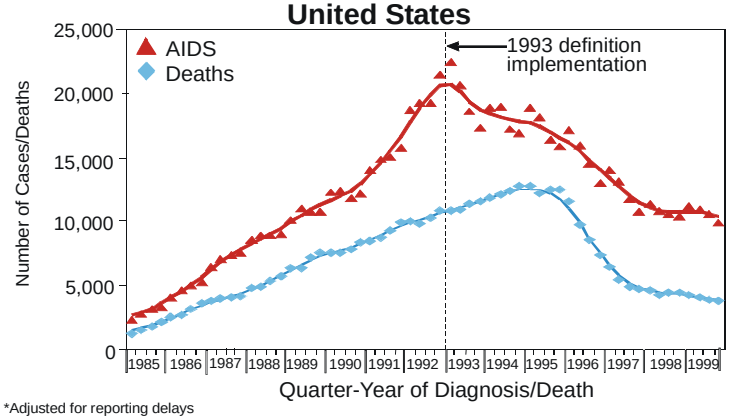
Perinatally Acquired AIDS Cases* by Quarter-Year of Diagnosis, 1985-1999, United States



*Adjusted for reporting delays and unreported risk; data reported through June 2000

Estimated Incidence of AIDS and Deaths of Adults/Adolescents with AIDS*, 1985-1999, United States



*Adjusted for reporting delays

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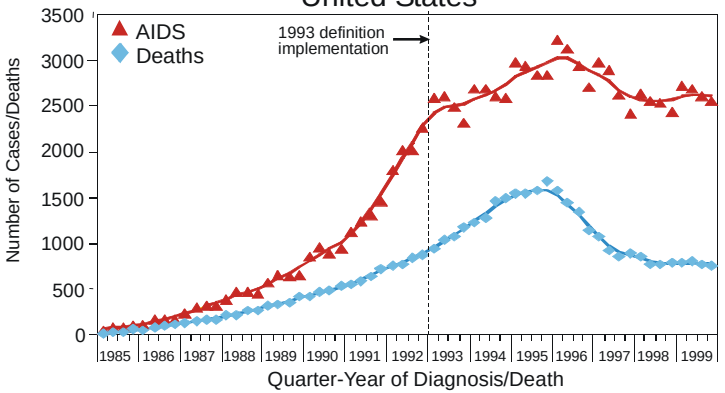

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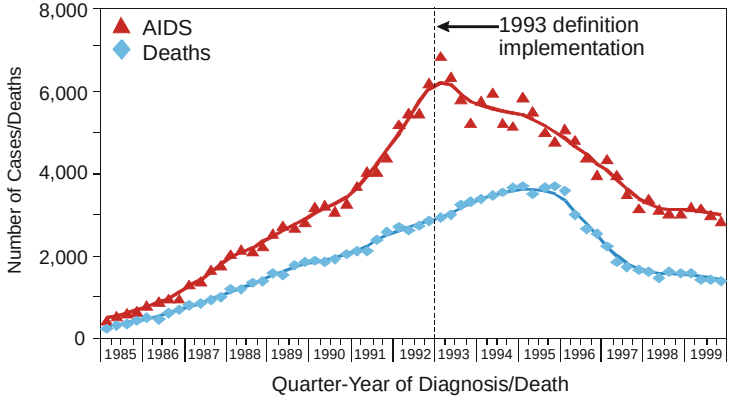

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